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| ROSS J. OEHLER | | | MONDESI, ROBERT B | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | A 11 41 A1 | | | | |
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| | Application No. | Applicant(s) | | | |
| Office Action Summany | 10/076,631 | HABERMANN, PAUL | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Robert B. Mondesi | 1653 | | | |
| The MAILING DATE of this communication a Period for Reply | ppears on the cover sheet with | the correspondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perior Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNIC. 1.136(a). In no event, however, may a reput of will apply and will expire SIX (6) MONT ate, cause the application to become ABA | ATION. lly be timely filed HS from the mailing date of this communication. NDONED (35 U.S.C. § 133). | | | |
| Status | | | | | |
| 1) Responsive to communication(s) filed on 29 | September 2005 | | | | |
| , | nis action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under | | | | | |
| Disposition of Claims | | , | | | |
| 4) ☐ Claim(s) 1-20 is/are pending in the application 4a) Of the above claim(s) 4,5 and 13-20 is/are 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-3 and 6-12 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and | e withdrawn from considerati | on. | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Exami 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct the correct of | ccepted or b) objected to be ne drawing(s) be held in abeyand ection is required if the drawing(s | e. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.121(d). | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a li | ents have been received. ents have been received in Apriority documents have been reau (PCT Rule 17.2(a)). | oplication No received in this National Stage | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Notice of Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6) Other: | | | | | |

DETAILED ACTION

Response to restriction requirement

Applicants' election with traverse of Invention I, Claims 1-3 and 6-12 in amendment, filed May 17, 2005 is acknowledged. The traversal is on the ground(s) that the protein of claims 4 and 5 requires the DNA sequence recited in claims of Group I to encode it and with regards to purification the claims as written require some type of purification to be performed, if recombinant methods are used. Applicants urge further that the claim is to a biochemical composition of matter and not to a process of use, the uses include expressing the DNA in an expression vector or hybridizing the DNA in a hybridization assay. This is not found persuasive. Applicants response is slightly confusing as it is not clear what is being traversed; nonetheless, the reason why the examiner pointed out the different uses of the compositions, was to indicate that the two mentioned products are distinct because they can be used in different processes. Furthermore, the examiner would like to point out that, even if the applicants' arguments were persuasive; firstly the two Groups have different classifications and secondly, it is noted that, while publications disclosing polynucleotide sequences typically disclose the corresponding polypeptide sequences, it is false to assume the only source of disclosure of a polypeptide is one in which the polynucleotide sequence is disclosed. Thus a separate search is required for the invention of Group II. Therefore the requirement is still deemed proper and is made FINAL.

Applicants' further election of election with regards to Px, Sx, Bn, Z1, Z2, T, protein Y and Protein Ym in response to the restriction requirement mailed March 24,

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2005 and notice of non-compliant mailed June 7, 21 2005 is acknowledged. Applicants elected the following variables: Px = ADH2 promoter, Sx = Alpha factor leader sequence, Bn = chemical Bond, Z1 = lysine, Z2 = arginine, T = 3' interleukin 2 sequences, protein Y = miniproinsulin and protein Ym = 0. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL.

Claims 1-3 and 6-12 are pending and currently under examination.

Priority

The current application filed on February 19, 2002 claims priority to provisional application 60/270,592 filed on February 23, 2001 and foreign application 10108100.6 filed on February 20, 2001. A certified copy of foreign document 10108100.6 has been provided.

Information Disclosure Statement

The Information Disclosure sheets (IDS)s filed September 13, 2002 and November 7, 2002 have been received and are signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

The disclosure is objected to because of the following informalities:

The use of the trademark REFLUDAN has been noted in this application. It should be <u>accompanied by the generic terminology</u>.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 (claims 2-3 and 6-12 dependent therefrom) are drawn to a genus of nucleic acid sequences as encompassed by the claims. For claims drawn to a genus, MPEP § 2163 states the written description requirement for claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and

function, or by combination of such identify characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species, which are adequately described, are representative of the entire genus.

Thus, when there is substantial variation within the genus, as is the instant case, one must describe a sufficient variety of species to reflect the variation within the genus. The specification discloses only three species of the genus of claimed nucleic acid sequences, i.e., the nucleic acid sequences obtained in Examples 1-3 of the instant specification (see pages 14-22 of the instant specification). While it is noted that the specification describes the structures of additional representative species of signal sequences (represented by Sx in claim 1) at pages 17-18, the specification fails to describe any additional representative species of the claimed genus of nucleic acid sequences, which encompasses species that are widely variant in structure. As such, the disclosure of the three representative species of nucleic acid sequences is insufficient to be representative of the attributes and features of all species encompassed by the recited genus of nucleic acid sequences. Given the lack of description of a representative number of nucleic acid sequences, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence prepared as described in Examples 1-3 of the specification and having the signal sequences as set forth at pages 17-18 of the specification, does not reasonably provide enablement for all the possible nucleic acid molecules suggested by the general formula of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use and make the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and

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(8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

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1-2. Breadth of the claims and the nature of the invention.

The claims are overly broad in scope: Claim 1 (claims 2-3 and 6-12 dependent therefrom) are so broad as to encompass a vast number of nucleic acid sequences

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comprising <u>any</u> promoter sequence, any signal or leader sequence <u>any</u> nucleic acid sequence encoding a transport peptide, optionally encoding hirudin or <u>any</u> hirudin derivative, <u>any</u> nucleic acid sequence encoding a protein that is produced and secreted in yeast, optionally a mini-proinsulin encoding nucleic acid sequence or <u>any</u> derivative thereof, and any untranslated expression-enhancing nucleic acid. The broad scope of claimed nucleic acid sequences is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of promoters,

3. The state of prior art.

The art provides evidence for the high degree of unpredictability in altering a protein sequence with an expectation that the protein will maintain the desired activity/utility. For example, Branden et al. ("introduction to Protein Structure", Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability. they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). While it is acknowledged that this reference was published in 1991, to date there remains no certain method for reasonably predicting the effects of even a single amino acid mutation on a protein.

4. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

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5. The level of predictability in the art.

The high level of unpredictability in the art: The amino acid sequence of a protein determines the protein's structural and functional properties. Predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. The positions within an encoding nucleic acid's sequence where modifications can be made with a reasonable expectation of success in obtaining an encoded polypeptide having the desired activity/utility are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. In this case, the necessary guidance has not been provided in the specification as explained above. Thus, a skilled artisan would recognize the high degree of unpredictability that the entire scope of nucleic acid sequences, including those encoding hirudin derivatives and mini-proinsulin derivatives, would encode a polypeptide having the desired anticoagulant and insulin activities.

6-7. The amount of guidance present and the existence of working examples.

The lack of guidance and working examples: the specification provides only three working examples of the claimed nucleic acid sequences, i.e., those three nucleic acid sequences prepared as described in Examples 1-3 of the specification. The

specification provides further guidance for additional signal sequences that may be used to substitute the signal sequence in the nucleic acid sequences constructed according to Examples 1-3 in the specification (see pages 17-18 of the specification).

However, these working examples and guidance regarding additional signal sequences fail to provide the necessary guidance for making the entire scope of claimed nucleic acid sequences.

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue: while methods of generating variants of a given protein, e.g., site-directed mutagenesis, are known, it is not routine in the art to screen for all proteins having a substantial number of modifications having any function, as encompassed by the instant claims. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the ad to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is

unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the phrase "hirudin derivative" and claim 3 recites the phrase "blood clotting factor derivative"; however the specification of the present application does not define the nature of the mentioned derivatives, for example are the mentioned derivatives chemical derivatives, structural derivatives or enzymatic derivatives. In another words it is not clear as to what manner the said hirudin or blood-clotting factor has been derivatized.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. (US patent 5,434,073) in view of Price et al., 1987 (Cited in the IDS filed September 13, 2002).

The claims are drawn to a nucleic acid sequence as set forth in claim 1, optionally wherein Y is a mini-proinsulin derivative, a vector or plasmid comprising said

nucleic acid sequence, a host cell comprising said vector or plasmid, and methods for the production of a fusion protein.

Dawson et al. generally teach nucleic acids encoding hirudin fusion proteins. For example, Dawson et al. teach an expression vector encoding a hirudin-hirudin fusion protein comprising a galactose regulated promoter, a nucleotide sequence encoding an alpha-factor pro-peptide, a linker of Ser-leu-Asp-Lys-Arg, an N-terminal hirudin, a Ile-Glu-Gly-Arg linker, a C-terminal hirudin or a C-terminal streptokinase, and a yeast PGK terminator (See Example 1, columns 1 1-13 and Examples 8-9, columns 25-27).

Dawson et al. teach expression of the hirudin-hirudin or hirudin-streptokinase fusion proteins by culturing *Saccharomvces cerevisiae* transformed with the expression vector, followed by isolation of the fusion protein (Example 2, columns 13-14 and Example 15, column 32).

Dawnson et al. do not teach a nucleic acid vector comprising a nucleic acid sequence comprising and ADH2 promoter and an alpha factor leader sequence.

Price et al teach a nucleic acid vector comprising a nucleic acid sequence comprising and ADH2 promoter and an alpha factor leader sequence.

Price et al. teach that the expression and secretion of two lymphokines, murine granulocyte-macrophage colony-stimulating factor(MuGM-CSF) and bovine interleukin-3 (BoIL-2), to levels of 50-60 mg per liter were achieved by placing these cDNAs in a *Saccharomyces cerevisiae* expression vector that utilized the yeast alcohol dehdrogenase-2 (ADH2) promoter and alpha-factor leader peptide (Page 287, abstract, lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a vector that utilized the yeast alcohol dehdrogenase-2 (ADH2) promoter and alpha-factor leader peptide for an expression vector encoding a hirudin-hirudin fusion protein because an inducible promoter such as ADH2 allows for the control of the expression of foreign proteins in yeast and a leader peptide such as the alpha factor peptide allows for the secretion of foreign proteins (expressed in yeast) as taught by Dawson et al. and Price et al., 1987, see Price et al. Page 288, column 1, lines 6-10.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claim 1 is provisionally rejected under the judicial created doctrine of obviousnesstype double patenting as being unpatentable over claim 4 of US non-provisional application 10/076,634 (1634 Application). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims) because the examined claim is either anticipated by, or would have been obvious over, the reference claims). See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the instant application is drawn to a nucleic acid sequence having the formula as set forth in the claim. Claim 4 of the '634 Application is drawn to a nucleic acid sequence having the formula as set forth in the claim. The claims differ in that the elements of the formula vary between the two claims and the protein(Y) of claim 1 of the instant application is limited to a nucleic acid encoding a protein that is produced and secreted by yeast (although the protein itself is not limited to being produced and secreted in yeast). The portion of the specification of the '634 Application that supports the claimed nucleic acid includes two embodiments of claim 4, i.e., a nucleic acid encoding a Ser-hirudin GNSAR-simian proinsulin fusion protein (pages 18-20) and an Ala-hirudin-R-simian proinsulin fusion protein (pages 20-22). Claim 1 of the instant application cannot be considered to be patentably distinct over claim 4 of the '634 Application when there is a specifically recited embodiment in the '634 Application that would anticipate claim 1.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US nonprovisional application 10/076,632 ('63& Application). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims) because the examined claim is either anticipated by, or would have been obvious over, the reference claims). See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi. 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 2 of the instant application is drawn to a nucleic acid sequence having the formula set forth in the claim. Claim 1 of '632 Application is dawn to a nucleic acid molecule as set forth in the claim. The claims differ in that the elements of the formula vary between the two claims. The portion of the specification of '632 Application that supports the claimed nucleic acid includes at least one embodiment of claim 1, i.e., a nucleic acid encoding a hirudin-miniproinsulin fusion protein (pages 14-17). Claim 2 of the instant application cannot be considered to be patentably distinct over claim 1 of the '632 Application when there is a specifically recited embodiment in '632 Application that would anticipate claim 2. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B Mondesi Patent Examiner Group 1653

Robert

JON WEBER
SUPERVISORY PATENT EXAMINER